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February 17, 2012

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David R. Saliwanchik, Patent Attorney

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT  
Patent Application  
Docket No. SPO.129

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Philip A. Dubois  
Art Unit : 1781  
Applicants : Hisae Kume *et al.*  
Serial No. : 10/593,550  
Conf. No. : 4478  
Filed : September 19, 2006  
For : Antibacterial Compositions

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§1.97 AND 1.98

Sir:

The above-identified patent application was filed in the U.S. Patent Office as a national application under 35 USC §371.

In accordance with 37 C.F.R. § 1.56, the reference listed on the attached Form PTO/SB/08 is being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of the cited document is attached.

Please note that the reference JP 2004/051494 (F1) is in a foreign language. However, a concise explanation of the reference has been provided for the Examiner's convenience, copy attached.

The undersigned hereby certifies that the item of information contained in this statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.

It is respectfully requested that the Examiner indicate consideration of the cited reference by returning a copy of the attached Form PTO/SB/08 with initials or other appropriate marks. If any additional fee is required, or to credit any overpayment, please use Deposit Account No. 19-0065.

The applicants respectfully assert that the substantive provisions of 37 C.F.R. §§ 1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,



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DRS/kmm

Attachments: Form PTO/SB/08 (1 page)  
Copies of reference cited  
Copy of concise explanation of cited reference

Concise Explanation of Japanese Reference

Japanese Patent Application *Kokai* Publication No. 2004-51494

Publication date: February 19, 2004

5 Title: Enteral nutrients

This patent document is cited in the prosecution of the corresponding Korean application (Korean Application No. 10-2006-7022476) as disclosing an enteral nutrient containing proteins, fats and carbohydrates at energy ratios of 10-40%, 10-40% and 40-80%,  
10 respectively. The Korean Patent Office asserts that the fluid foods contemplated in the corresponding application include such an enteral nutrient, that this document describes a composition comprising a plant-derived oil, such as rapeseed oil, that this document also describes enteral nutrients containing casein sodium, dairy proteins, dextrin, fructose, rapeseed oil and such, and that this document further teaches a process for preparing an enteral nutrient,  
15 comprising the steps of dissolving the components of the nutrient in hot water with stirring, and sterilizing the mixture.

The invention of this document provides enteral nutrients which could improve protein metabolism, immune ability, intestinal mucosal functions, and such through administration, for  
20 example, to patients receiving surgery or patients with severe infection.

The invention relates to liquid enteral nutrients having an osmotic pressure of 300 to 600 mOsm/kg, an amino acid score of 100, and comprising the following substances as main ingredients:  
substance A: nitrogen source substances of 10-40 energy % to the total energy source, and  
25 comprising proteins, glutamine-containing peptides, and amino acids;  
substance B: lipids of 10-40 energy % to the total energy source;  
substance C: carbohydrates of 40-80 energy % to the total energy source;  
substance D: an emulsifier; and  
substance E: water.

30 The glutamine-containing peptide added to the enteral nutrient is expected to show an effect of improving protein metabolism, immune ability, intestinal mucosal functions, and such. It is not converted after dissolving in water or heat sterilization into pyroglutamate which does not show these effects.

An osmotic pressure of 300 to 600 mOsm/kg represents an osmotic pressure which  
35 imposes little burden to the body, and an amino acid score of 100 is used so that the effect of the glutamine-containing peptide is most effectively exhibited.

The Examples show methods for preparing various enteral nutrients and measuring various parameters (such as protein, glutamine, lipid, and carbohydrate contents; amino acid score; osmotic pressure; pH; and palatability) of the prepared enteral nutrients. However, the antibacterial effects of the enteral nutrients are not discussed with showing experimental results  
5 or data.

The enteral nutrients prepared in the Examples are shown in Table 1.

Table 1

	Composition (Weight %)	Example 1	Example 2	Example 3	Example 4	Example 5	Example 6	Example 7	Example 8	Example 9
		Substance A	Substance B	Substance C	Substance D	Substance E	Rest	Other substances	Shown in Table 2	Total
Results	Glutamine-containing peptide	1.5	1.5	1.5	1.5	1.5	1.5	—	1.5	1.5
	Casein sodium	3	3	3	3	3	3	4.2	3	3
	Lactoprotein	2	2	2	2	2	2	2	2	2
	L-methionine	0.02	0.02	0.02	0.02	0.02	0.02	—	—	0.02
	L-threonine	0.01	0.01	0.01	0.01	0.01	0.01	—	—	0.01
	L-tryptophan	0.02	0.02	0.02	0.02	0.02	0.02	—	—	0.02
	Rape seed oil	1.4	1.4	1.4	1.4	1.4	1.04	1.4	1.4	1.92
	Medium chain fatty acid	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
	Fish oil	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08
	Dextrin with DE11	9	9	9	9	9	9	9	9	9
	Dextrin with DE25	3	3	3	3	3	3	3	3	3
	Fructose	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
	Succinic acid monoglyceride	0.39	0.33	0.26	0.65	—	0.6	0.39	0.39	—
	Citric acid monoglyceride	0.26	0.33	0.39	—	0.65	0.5	0.26	0.26	—
	Water	Rest								
	pH adjuster	Rest								
	Sodium hydroxide	0.07	0.07	0.07	0.07	0.07	0.07	—	0.07	0.07
	Other substances	Shown in Table 2								
	Total	100	100	100	100	100	100	100	100	100
	Protein content (g/100ml)	5.5	5.5	5.5	5.5	5.5	5.5	5.5	5.5	—
	Glutamine content (g/100ml)	0.75	0.75	0.75	0.75	0.75	0.75	0.2	0.75	—
	Amino acid score	100	100	100	100	100	100	100	70	—
	Lipid content (g/100ml)	2.6	2.6	2.6	2.6	2.6	2.6	2.6	2.6	—
	Total calories (kcal/100ml)	100	100	100	100	100	100	100	100	—
	Carbohydrate content (g/100ml)	13.7	13.7	13.7	13.7	13.7	13.7	13.7	13.7	—
	Osmotic pressure (mOsm/kg)	480	472	479	499	493	461	472	476	—
	Viscosity (cp)	10	10	10	10	10	7	9	9	—
	Average particle diameter (μm)	0.18	0.21	0.20	0.28	0.26	0.18	0.19	0.19	—
	pH	6.7	6.7	6.7	6.7	6.7	6.1	6.7	6.7	—
	State of liquid	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	x
	Palatability	⊙	⊙	⊙	⊙	⊙	⊙	⊙	⊙	x
	Preservation test: osmotic pressure (mOsm/kg)	488	483	495	512	507	—	480	483	—
	Preservation test: viscosity (cp)	10	12	12	18	14	—	10	10	—
	Preservation test: average particle diameter (μm)	0.18	0.24	0.26	0.77	0.58	—	0.19	0.19	—
	Preservation test: pH	6.5	6.5	6.5	6.5	6.5	—	6.5	6.5	—
	Preservation test: state of liquid	⊙	○	○	△	△	x	⊙	⊙	—
	Preservation test: palatability	⊙	○	○	△	△	x	⊙	⊙	—